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Food Safety And Inspection Service
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AUDIT REPORT FOR ICELAND

OCTOBER 5 – OCTOBER 19, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Iceland's meat inspection system October 5 through October 19, 2000. The five establishments certified to export meat product to the United States were audited. All were slaughter and processing establishments.

The last on-site audit of Iceland's inspection system was conducted in October 1999. At that time, four establishments certified to export meat product to the United States were audited. All establishments, and two official residue testing laboratories visited were acceptable. Among the deficiencies observed in these establishments, and the residue testing laboratories were:

- Peeling paints and rust spots in Ests. 22, 23, and 31.
- Boneless meat inspection not being done.
- Inadequate written Sanitation Standard Operating Procedures (SSOPs), and lack of operational sanitation observations in establishments 31.
- Lack of Hazard Analysis and Critical Control Points (HACCP) verification procedures in establishments 31.
- Inadequate laboratory check-sample program.

All of these deficiencies had been corrected.

During January to September 30, 2000, Iceland exported 17,606 pounds of fresh/frozen lamb product to the United States. At the U.S. port-of-entry on re-inspection, 400 pounds were rejected for missing shipping marks and processing defects.

PROTOCOL

The on-site review was conducted in four parts. One part involved visits with various Iceland meat inspection officials, Feed, Seed and Fertilizer Inspectorate, field District Veterinary Officers, residue control and analytical laboratories to discuss oversight programs and practices, including enforcement activities. The second entailed discussions and audit of inspection system control documents at the headquarters. The third included on-site visits to five establishments certified to export to the United States. The fourth was a visit to two official laboratories performing analytical testing of samples for the national residue and microbiological monitoring program, and one establishment owned private laboratory and one official dairy product laboratory (contacted by an establishment) testing generic *E. coli.*

The auditor also visited a livestock farm to verify animal husbandry practices and proper use and control of antibiotics, drugs, and other regulated chemicals or compounds.

Iceland's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation of Hazard Analysis and critical Control Point (HACCP) systems, and the *E. coli* testing program, and (5) enforcement controls, including the testing program for species identification. The emphasis was placed on Iceland's National Residue Control Program to verify information provided by Iceland on the national residue control system, which included laboratory testing, intra- and inter-agency legislation and regulatory authority, and compliance enforcement.

During on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/ adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection controls were found to be in place in all establishments. However, the following deficiencies in establishment operations, pathogen reduction (PR)/HACCP, and the national residue control program were noted:

In all establishments, the fully or partially wrapped product was stored in freezers on floors, and was in contact with walls and/or ceilings. In Ests. 23, 31, and 81, carcasses were inadequately trimmed before cut up and/or boning.

The species identification testing was not being done.

In all establishments visited, establishment personnel poorly understood the HACCP plan. The critical control points (CCPs) were identified at points where establishments could not prevent, reduce or eliminate hazards likely to occur, and pre-shipment verification was not being performed. Est. 23 had not conducted analysis for hazards likely to occur in terms of chemical, biological or physical hazards. Est. 40 did not describe corrective and preventive actions to be taken in response to a process control failure.

The procedures for generic *E. coli* testing varied from U.S. requirements. One in 900 carcasses were sampled three times a week from legs, breast and flank. Sheep over five months old were

not tested. The establishments did not evaluate test results using statistical process control to determine what variation in test results was within normal limits.

Iceland's residue control program, in general, was comparable with U.S. requirements. However, the analytical turn-around time was over four months.

Entrance Meeting

On October 5, 2000, at the request of U.S. Embassy, an entrance meeting was held with Mr. Robert E. Sorenson, Deputy Chief of Mission, and Ms. Borghildur Magsúsdóttir, Economic/Commercial Assistant. The auditor briefed them on the Food Safety and Inspection Service's (FSIS) policy on the subject, and provided them up-to-date information on Iceland's equivalence status.

A technical meeting was also held at the Iceland's Ministry of Agriculture, Veterinary Services headquarters on October 5, 2000, and was attended by Dr. Halldór Runólfsson, Chief Veterinary Officer (CVO), and Dr. Sigurður Örn Hansson, Deputy CVO and Chief Meat Inspection, and Dr. Hussain Magsi, International Audit Staff Officer, USDA, FSIS, Field Operations. Topics of discussion included:

1. Audit itinerary.
2. Use of nutritional or geographic claim labels.
3. SSOPs, HACCP, and generic *Escherichia coli (E. coli)* testing.
4. National residue control program.
5. FSIS policy on 'listing and delisting' of establishments.
6. Compliance enforcement.

Iceland's inspection system officials stated that corrective measures had been initiated to prevent the recurrence of deficiencies noted during the previous FSIS audit in October 1999.

Headquarters Audit

There had been no changes in staffing or the inspection system organization since the last U.S. review of Iceland's meat inspection system in October 1999.

To gain an accurate overview of the effectiveness of inspection controls, the FSIS auditor requested that the audits of the individual establishments be lead by the inspection officials who normally conduct the periodic reviews for compliance with U.S. requirements. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of the inspection system documents, which included:

- Organizational structure of Veterinary Services in Iceland
- New initiatives and regulatory changes (Act, regulation, and policy).
- Internal audit, and monthly supervisory reports.

- Food safety initiatives such as SSOP, HACCP programs generic *E. coli* testing, and species testing.
- Performance standards for sanitation, facilities, and equipment, including water potability and insect and rodent control.
- Slaughter and processing inspection procedures and standards including labels approval, boneless inspection, etc.
- Epidemiology, and zoonotic trends in Iceland including control of products from livestock disease conditions.
- National residue control program regulations and guidelines.
- Livestock husbandry practices, including use of drugs and chemical and feed additives, and disease control.
- Compliance enforcement.

The concerns that arose as a result of this audit have been discussed under relevant headings in this report.

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by Iceland to export meat product to the United States were full-time or part-time employees receiving no remuneration directly from either industry or establishment personnel.

In Iceland, under the Minister of Agriculture, the Veterinary Service is operated by a Chief Veterinary Officer (CVO), Dr. Halldór Runólfsson, and Dr. Sigurður Örn Hansson, Chief Meat Inspection (CMI). At the Reykjavik headquarters, there is a diagnostic laboratory, and a technical veterinary staff of nine specialists: fur animals, swine diseases, fish diseases, poultry diseases, cattle and sheep diseases, horse diseases, mastitis and milk hygiene/diseases, meat hygiene/inspection, and import/export. The headquarters staff administers field operations in 14 districts.

The District Veterinary Officers manage field operations under the supervision of the CVO and the CMI. They monitor slaughter and processed product establishment operations, tend to animal health care and husbandry of livestock, conduct internal audits of slaughterhouses, and perform compliance enforcement investigations. Continuous inspection is provided in all slaughterhouses during operations. Veterinary and auxiliary inspectors are hired on permanent or temporary basis, if needed. In large volume establishments, additional veterinarians are also employed, such as in Ests. 31 and 81. Additional veterinarians could be hired to assist in disease control and disease prevention activities.

In export meat slaughter establishments, one to three food inspectors (auxiliary) are assigned to perform meat inspection. The auxiliaries are employed part-time. There are several trained auxiliaries available, and they are called upon to serve whenever and wherever needed. All veterinarians and auxiliaries are paid directly by the government through public funds. These funds are user-fees levied from the farmers or packers for services rendered.

Establishment Audits

Five establishments (Ests. 22, 23, 31, 40, and 81) were certified to export meat products to the United States. With the exceptions described in the text, generally the inspection and establishment system controls were in place to prevent, detect and control contamination and adulteration of the product.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to the U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Inter-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The auditor visited two official laboratories that conduct analyses for some of the required residues. These were the Institute for Experimental Pathology in Keldur, and the Icelandic Fisheries Laboratory in Reykjavik. These laboratories analyze a wide range of antibiotics, cobalt, arsenic, mercury, and lead. The Keldur laboratory also conducts species verification testing.

Both laboratories were well equipped and staffed with competent and well-qualified staff. Effective controls were in place for sample handling and frequency, equipment operation and printouts, minimum detection level, recovery frequencies, and percent recoveries. The analytical methods used were standard or internationally validated. However, samples were not analyzed in a timely manner. The turn around time for analysis and results was over four months.

The auditor also visited two laboratories performing generic *E. coli* testing for the establishments. One was a laboratory owned by Est. 81 and was located in a sister plant. The other was a branch of the Icelandic Fisheries Laboratories (routinely testing milk products) which tested generic *E. coli* for Est. 40 (on user-fee basis). Both laboratories met U.S. requirements.

Establishment Operations by Establishment Number

The following operations were being conducted in the establishments visited:

22 – Ovine, bovine and equine slaughter, cut up and boning
23 – Ovine, bovine and equine slaughter, cut up and boning
31 – Ovine slaughter, cut up, and boning
40 – Ovine, bovine and porcine slaughter, cut up, and boning
81 – Ovine, bovine, porcine and equine slaughter, cut up and boning

SANITATION CONTROLS

Based on the on-site audits all establishments visited, with the exceptions discussed below, met U.S. sanitation performance standards for establishment grounds and pest management, establishment construction, lighting, ventilation, plumbing and sewage disposal, water supply, ice and solutions re-use, dressing rooms, lavatories and toilets, equipment and utensils, sanitary operations (food contact/non-contact surfaces, employee hygiene (cleanliness, clothing and health), and tagging (in-sanitary equipment, utensils, rooms and areas). However, following deficiencies were noted included:

- In all establishments, partial or fully wrapped product was stored in freezers on floors and was in contact with walls and/or the ceilings.
- In Ests. 23, 31, and 81, carcasses were not properly trimmed before cut up/boning.

Sanitation Standards Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

ANIMAL DISEASE CONTROLS

No reportable animal diseases had been recorded since the previous FSIS audit.

RESIDUE CONTROLS

The auditor conducted an in-depth audit of Iceland's national residue control program to verify information provided by Icelandic Government in February 2000 in response to an FSIS questionnaire. This on-site audit included discussions with key officials in Ministry of Agriculture's various agencies: (1) meat inspection, livestock husbandry practice, use and distribution of feed additive/supplements, animal medicaments/drugs, and fertilizers, (2) audit of legal authority documents, residue monitoring plan, and compliance enforcement, and (3) audit of two national residue control monitoring laboratories in Keldur and Reykjavik, Iceland.

- The auditor visited a livestock farm (over 100 years old) located in Borgarnes, discussed husbandry and animal health practices with the farmer and the local veterinarian. The observations and records review included inventories and authorized use of drugs and supplemental compounds/feed additives, and withdrawal time before slaughtering. Discussions were held with Dr. Olafur Gudmundsoin, Director, Feeds and Fertilizer Inspectorate, Ministry of Agriculture on the use and distribution of additives in animal feeds and supplements for Feed, Seed and Fertilizer.

The national residue program includes (1) identifying and evaluating drugs, pesticides and other chemical compounds of concern by slaughter class and/or egg product, (2) capability to analyze compounds of concern reliability, (3) appropriate regulatory follow-up of reports of violative tissue residues in meat, poultry and egg product, (4) collection, analysis, and reporting of these activities, and (4) anticipated testing plan to analyze compounds of concern reliability for specific slaughter classes and/or egg products for a specified time period.

The auditor performed an on-site residue control program using evaluation Iceland's response to FSIS questionnaire as template, using a checklist on "Criteria for Assessing the Adequacy of the Residue Control Program for Meat, Poultry, and Egg Products". The criteria for assessing the adequacy of the residue control program covered:

- Background - information on animal husbandry, availability of drug usage, agricultural chemicals and incidence of environmental contaminants and pesticides.
- Organization and legal authority - to describe the specifications of the legal basis and the organization of the government's activities to prevent contamination of food product with chemical residues.
- Residue plan design - to obtain information to understand the basis and the process used to design the residue plan.
- Residue plan operations - to obtain information on the basis and actual operation of residue plan.
- Compliance and enforcement - to obtain information about actions taken to deal with residue findings as they occur.
- Laboratories - to obtain information on the general capabilities of analytical laboratories on their ability to assure the validity and reliability of test data.

- The Icelandic residue control programs for meat and meat products is monitored by following laboratories:

1. Institute for Experimental Pathology, Keldur, Iceland
2. Icelandic Fisheries Laboratory, Reykjavik, Iceland
3. National Food Laboratory, Helsinki, Finland
4. Veterinary School Laboratory, Oslo, Norway

The Keldur and Reykjavik official laboratories analyze antibiotics, and trace elements (arsenic, cobalt, lead, and mercury. Contracted laboratories in Helsinki, Finland and Oslo, Norway test all other chemical compounds/drugs. The Helsinki laboratory analyzes meat product samples for stilbenes (DES, hexoestrol and dienoestrol), thyrostats (zyranol and trenbolon), sulfonamides (sulfanilamide, sulfadiazine and sulfamethazine), antibiotics (chloramphenicol and tetracyclin), anthelmintic (ivermectin), chlorinated hydrocarbons, organo-dichlorvos phosphorus compounds (diazinon, fenchlorphos, malathion, fenthion, famfur, coumphos and trichlorphon), and □-agonists. The Helsinki laboratory analyzes anthelmintic (benzimidazol).

The documents audit of the sampling and results available at national meat inspection headquarters indicated that analytical turn-around time for all compounds tested in all laboratories was over four months. FSIS's expected turn-around time is 3-work weeks.

The auditor visited Helsinki, Finland laboratory in September 2000 during FSIS on-site audit of Finland's meat inspection system. The laboratory met U.S. requirements. The Oslo laboratory is not audited by FSIS. Currently Norway does not export meat product to the United States. Therefore verification could not be done.

HACCP Implementation

All establishments approved to export meat products to the U.S. were required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instruments used accompanies this report (Attachment B).

The HACCP program was found to meet the basic FSIS regulatory requirements. However, following variances were noted:

- The establishment personnel did not understand HACCP plans.
- In all establishments visited, the critical control points (CCPs) were identified at points where establishments could not address the hazard in the process to prevent, reduce or eliminate the hazards, and pre-shipment verification was not performed.
- Est. 23 did not conduct analysis for hazards likely to occur in terms of chemical, biological or physical hazards.
- Est. 40 did not describe corrective and preventive actions to be taken in response to process control failure.

Testing for generic *E. coli*

Iceland has adopted regulatory requirements for *E. coli* testing. The establishments audited were required to meet the basic FSIS regulatory requirements for *E. coli* testing and were audited according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The documents audit showed that subsequent to promulgation of the January 14, 1999 regulation on, "Internal control in Slaughterhouses and their Meat Packing Centers", the "Regulations on Sampling and Testing for generic *E. coli* in Sheep Product" were introduced on June 7, 2000 and implemented in August. The auditor discussed procedures, and on-site verified their effectiveness. The generic *E. coli* testing program deviated from U.S. requirements as follows:

- Instead of the required one in 300 sheep and/or predominant slaughtered species sampling year round, only lambs (5-month old) were being sampled at the rate of one in 900 during September/October only.
- Older sheep were not tested.
- Instead of keeping the sample in 25-ml solution and disallowing cut (excision) method, the samples were kept/soaked in 10 ml, and the excision sampling was permissible.

- Instead of flank, brisket and rump, the swab samples were collected from legs, breast and flank.
- The establishment did not record or use process control technique (charting or plotting the results overtime) to determine what variation in test results was within normal limits. The normal limits were not established.

ENFORCEMENT CONTROLS

Inspection System Controls

The establishment's system conducts boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product.

Iceland's inspection system performs at least one internal audit and monthly audits of U.S.-certified establishments.

Residue Controls

Iceland suspends export of meat product to the United States from the establishments where residue violations are found.

Testing for *Salmonella* Species

It does not apply. Only lamb/sheep are slaughtered for export to the United States.

Testing for *Listeria monocytogenes*

It does not apply. Currently ready to eat product is not prepared for U.S. market.

Species Verification Testing

At the time of this audit, Iceland was not exempt from species verification testing requirement. However, there was no program in place for routine species verification of products in establishments where multiple species were processed.

The required species verification was not being done. Following the entrance meeting, the Inspection Service directed the inspectors to collect one sample from each U.S.-certified establishment monthly for species identification to the official laboratory in Keldur.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, no less frequently than

one such visit per month, during any period when the establishment is engaged in producing product that could be used for exportation to the United States.

The reviews were being performed by the Icelandic supervisor(s).

Enforcement Activities

The latest FSIS Quarterly Regulation and Enforcement Report (January – March 2000) was presented to the Icelandic meat inspection officials.

The compliance enforcement action pertaining to fines, product confiscation, and imprisonment were properly legislated, and actions were taken when laws were transgressed. The auditor reviewed three compliance enforcement case records:

1. Cattle slaughter establishment. A low capacity cattle slaughterhouse was not meeting hygienic requirements of the legislation. The establishment slaughtered 15 - 25 cattle once a month and a few young horses periodically.

   On March 30, 2000, the district veterinary officer (DVO) in-charge of the cattle slaughter establishment notified the Chief Meat Inspection (CMI) that the establishment was not complying with the inspection requirements and identified the following issues:
   - The roof over kill-floor and the chilling room was leaking.
   - The stunning area was not in accordance with regulations.
   - There was no sterilizer for the splitting carcasses.
   - Maintenance improvement program of buildings and equipment was needed.

   The CMI rescinded the grant of inspection registration until satisfactory improvement had been made. The roof was repaired, but other deficiencies still existed. The inspection grant was not reinstated. The company moved the operations to a sister facility.

2. Poultry slaughter and processing establishment. The establishment slaughtered over 40,000 poultry weekly and conducted cut up and boning operations. Food borne illness was reported following routine microbiological sampling result of campylobacter adulteration. On August 6, 1999, the CMI visited the establishment and concluded that the chilling of the product needed improvement, internal control had to be improved in accordance with Regulation No. 40/1999, and the facility maintenance.

   - On March 1, the CMI and the DVO reviewed the establishment.
   - On March 6, the findings were discussed with CVO, DVO, veterinary meat inspector-in-charge, and the poultry diseases specialist veterinary officer.
   - On March 8, the CVO sent a letter to the company requiring better cleaning and disinfecting of the transport crates, improved chilling of the product, improved maintenance, improved ventilation, improved internal control, and reduction in daily slaughter volume.

The company was given a deadline of April 1st to correct the deficiencies, and/or loose grant of inspection permit. Some of the correspondence audited:

- March 9 - the CVO and CMI met with the management, and discussed an action plan for improvement.
- March 11 - the CVO received a response to his letter of March 8 and illustrated the improvement plan.
- March 27 - the CMI verified that the company was implementing the improvement plan.
- March 30 - the CMI had a meeting with the management of their consultant and discussed compliance for the establishment system control by the company.
- On April 1 - the DVO reported that the campylobacter contamination of the product and the flock had significantly decreased and that the company had complied.

3. Antimicrobial residue violation. The experimental laboratory at Keldur, performing routine screening for antimicrobial residues in fresh meat, found 10 out of 30 pig kidney samples positive for antimicrobial residues in August1995. The results were confirmed using a chemical analytical method by an independent laboratory in Denmark for aminoglycosides.

   CMI directed the DVO to trace back the herd of origin and collect additional samples. On investigation it was found that the pigs were treated with dihydrostreptomycin 14-days before. The required withdrawal time for carcass was 14 days, and for offal 60 days. Matrices used for analysis were kidneys.

   CVO proposed a change in regulations of 60-days withdrawal period for both carcass and the offals, and the State Committee on pharmaceuticals approved the proposal.

Exit Meeting

An exit meeting was conducted in Reykjavik on October 19, 2000, and was attended by Dr. Halldór Runólfsson, Chief Veterinary Officer, Dr. Sigurður Örn Hansson, Chief Meat Inspection, Mr. Edward P. Brown, Economic Counselor, U.S. Embassy, Ms Borghildur Magsúsdóttir, Economic/Commercial Assistant, U.S., and Dr. Hussain Magsi, International Audit Staff Officer, USDA, FSIS, Field Operations.

The auditor discussed findings and observations made during the audit. These included deficiencies for (1) performance standards for sanitation, facilities, equipment and operations, (2) PR/HACCP, (3) national residue control program, and (4) species verification testing.

It was stated that:

(1) Establishment, Facilities and Equipment. The product had been removed off the floors, and away from the walls or ceilings under the supervision of the veterinary inspectors in all establishments. The carcass pre-trim procedures in Ests. 23, 31, and 81 had been re-assessed, and immediate actions had been taken to prevent product contamination.

(2) PR/HACCP. The regulations on generic *E. coli* testing had been modified and conformed to U.S. requirements. Modified plan regulations would be sent to FSIS as soon as possible. HACCP deficiencies were discussed with the industry, the plans would be reassessed and corrective actions taken. Establishment quality assurance personnel who developed the HACCP plans had food technology/science degrees, and HACCP was included in their academic curriculum. However, joint industry-inspectors formal HACCP training in CY-2001 would be planned to facilitate the understanding of FSIS initiated PR/HACCP systems.

(3) Residue Monitoring. The analytical turn around time for residue testing was being discussed with the subject matter experts and FSIS would be informed of the outcome as soon as the issue had been resolved internally.

(4) Species Verification Testing. Testing had been started at the rate of one-sample per month in all establishments.

Dr. Runólfsson requested that FSIS provide information on the availability of HACCP training for his staff and the industry. They would pay the expense. Mr. Brown asked him to provide specific information and that he would be pleased to explore possible avenues for training.

CONCLUSION

During this audit, five establishments were visited (Ests. 22, 23, 31, 40, and 81) and found to be acceptable. The overall establishment system was determined equivalent to that which FSIS requires in domestic establishments. However, deviations noted in the HACCP indicated inadequate training. Generic *E. coli* sampling sites and sampling and process control procedures varied with U.S. requirements. The national residue control program was comparable to U.S., however the analytical turn around time was over four months. The species verification testing was not being done.

(signed) Hussain Magsi, DVM, MS
Hussain Magsi, DVM, MS
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* (Not applicable)
E. Laboratory audit forms.
F. Individual Foreign Establishment Audit Forms.
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

Est. No.	1.Written program addressed	2. Pre-op sanitation addressed	3. Operational sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6.Responsible individual Identified	7. Documentation done daily	8. Dated and signed
22	√	√	√	√	√	√	√	√
23	√	√	√	√	√	√	√	√
31	√	√	√	√	√	√	√	√
40	√	√	√	√	√	√	√	√
81	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
1. The HACCP plan was validated using multiple monitoring results.
2. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. No	1. Flow diagram	2. Hazard analysis done	3. All hazards identi-fied	4. Use & users include.	5. Plan for each hazard	6. CCPs for all hazards	7.Monit. critical limits, and freq. specified	8.Correc-tive actions described	9. Plan valida-ted	10. Adeq. verific. Proc.	11. Adeq. Docum.	12. dated and Signed
22	√	√	√	√	√	*	√	√	√	**	√	√
23	√	√	No	√	√	*	√	√	√	**	√	√
31	√	√	√	√	√	*	√	√	√	**	√	√
40	√	√	√	√	√	*	√	No	√	**	√	√
81	√	√	√	√	√	*	√	√	√	**	√	√

* CCPs were not identified at points where establishments could address the hazards likely to occur in the process to prevent, reduce or eliminate the hazards.

** Pre-shipment verification was not done

Attachment C

Data collection instruments for *E. coli* testing

Following information was collected.

1. The establishment has a written procedure for testing for generic *Enterobacteriaceae.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. No.	1. Written procedure	2. Sample collector designated	3.Sampling location given	4.Predominant species sampled	5. Sampling at req. frequency	6.Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
22	√	√	√	√	No	No	√	√	No	√
23	√	√	√	√	No	No	√	√	No	√
31	√	√	√	√	No	No	√	√	No	√
40	√	√	√	√	No	No	√	√	No	√
81	√	√	√	√	No	No	√	√	No	√

Audit Checklist for Residue Control Program

[Following information was requested from Government of Iceland. The auditor for each question and request, on-site verified that the information presented by Iceland was correct. If information provided was correct, "YES" block was checked. If "No" block was checked, it stated what was found and any public health concerns. If the auditor was not responsible for auditing of a particular question, "Not Applicable" was written if more space was needed, it was continued on the back of the checklist and initial and date of entry.]

Following checklist was used to verify the information provided by Iceland for residue control program:

I. Background

The purpose of this section is to obtain general information about animal husbandry, availability of drug usage, agricultural chemicals and incidence of environmental contaminants and pesticides. This information will be used to determine equivalency with the United States' residue control program.

A. Provide total population figures of food animals by each species. YES ✓ NO __
B. Do animals slaughtered for export originate in another country other than the native country? YES ✓ NO __
C. Describe the husbandry practices commonly used for each species of animals slaughtered for export to the U.S. Information should describe such factors as:
   1. Type used for rearing animals. YES ✓ NO __
   2. Unique weather conditions which may require special housing. YES ✓ NO __
   3. Type of feed given to animals when slaughtered. YES ✓ NO __
   4. Typical age of animals when slaughtered. YES ✓ NO __
   5. Treatment for internal/external parasites (identify animal diseases or conditions commonly requiring treatment. YES ✓ NO __
   6. Marketing practices
   a. Average number of animals in slaughter lots. YES ✓ NO __
   b. Slaughter lots comprised of animals from one farm or from several farms/growers. YES ✓ NO__
D. What measures are taken to prevent exposure of food animals to pesticides? YES ✓ NO __
E. What measures are taken to prevent exposure of food animals to environmental or industrial contaminants? YES ✓ NO __

II. Organization and Legal Authority

The purpose of this section is to describe the specifications of the legal basis and the organization of the government's activities to prevent contamination of food products with chemical residues.

A. Are the preventive measures taken to satisfy the U.S. requirements handled through a central (National), regional (local) or special export residue program? YES ✓ NO __
B. Identify and summarize the laws and regulations concerning:
   1. Approval and use of food animal drugs and agricultural chemicals
   a. Provide lists of the following types of substances, specified by chemical names, permitted for use in your country:
   (1) Drugs permitted for therapeutic and preventive use in each species of food animals. YES ✓ NO _

(2) Prohibited substances. YES ✓ NO __
(3) Pesticides permitted for use in or on each species of food animals, permitted for crops used in food processing and storage facilities, or permitted for use in meat processing facilities.
YES ✓ NO __
(4) Environmental or industrial chemicals that are potential contaminants to food producing animals. YES ✓ NO __

b. For each drug and chemical listed in your residue plan, identify:
(1) The species
(2) The target tissue used as analytical control
(3) A list of the Maximum Residue Limits (MRL) [tolerance or action limits]
YES ✓ NO __

2. Specify the procedures used to approve the use of each substance listed in II.B.1.a.
YES ✓ NO __

C. Brief summarize the procedures employed for enforcing the above laws and regulation.
YES ✓ NO__

D. Provide a simple organizational chart and relationship to meat inspection system for:
1. Compound approval
2. Residue program design
3. Sample collection
4. Laboratory support
5. Enforcement
YES ✓ NO __

III. Residue Plan Design

The purpose of this section is to obtain information to understand the basis for your annual residue plan and the process used to design the residue plan.

A. Submit a copy of your annual residue plan, which clearly identifies all sampling plans (monitoring, surveillance or any other special testing programs in place) and identifies the target tissues to be analyzed, by species, for each specific residue compounds. Identify whether this is implemented on a calendar year or fiscal year. YES ✓ NO __

B. Describe the design of the sampling plan for animals to be tested for residues. Indicate whether the sampling plan is based on random sampling and statistical significance expected of the residue conclusions or whether the sampling plan is based on non-statistical design principles. In both cases, include the objective of the sampling program.
YES _✓ NO ___

The design is described as non-statistical, however, the plan does not include sampling the eligible species (all ages) throughout the normal slaughtering period of August through December, and occasional (as needed) slaughtering during January through July.

C. What criteria are used to determine whether a compound is included or deleted from testing program? YES ✓ NO __

D. What is the process for reassessing the residue plan How are data reviewed and analyzed to evaluate the progress: YES ✓ NO __

IV. Residue Plan Operations

The purpose of this section is to obtain information on the basis and actual operation of your residue plan.

A. Describe the implementation of you plan, providing any supplemental information that will help describe what you want o accomplish with the residue plan. YES ✓ NO __
B. Provide a summary of the instructions that are provided to the field personnel that describe sampling procedures, including but not limited to sample selection, collection, identification and security. YES ✓ NO __
C. What is the average time it takes for sample collection until final results are available to the inspector (or person responsible for action)? YES ✓ NO __

The response does not describe routine sampling results for other than 'suspect' animal samples. Routinely the results from Helsinki, Oslo, and national laboratories are available within 4 to 6 months from the time of sampling.

D. Describe the procedures for separating product destined to the U.S. in the case when domestic tolerances are higher. YES ✓ NO __
E. How are individual animals selected for sampling? How do you select the days on which samples are taken? YES ✓ NO __
F. Do inspection personnel use in-plant –screening methods? If so, what are these tests and how are they used (monitoring surveillance, animal selection, etc.)? Describe the validation of these tests for the intended purpose? YES ✓ NO __

V. Compliance and Enforcement

The purpose of this section is to obtain information about actions taken to deal with residue findings as they occur.

A. What actions are taken hen positive or violative results are determined for:
   (1) Drugs permitted for therapeutic and preventive use in each species of food animals. YES ✓ NO __
   (2) Prohibited substances. YES ✓ NO __
   (3) Pesticides permitted for use in or on each species of food animals, permitted for crops used in feed processing and storage facilities. YES ✓ NO __
   (4) Environmental or individual chemicals that are potential contaminants to food producing animals. YES ✓ NO __
B. What documentation of enforcement actions is maintained? YES ✓ NO __

V. Laboratories

The purpose of this section is to obtain information on the general capabilities of analytical laboratories and their ability to assure the validity and reliability of test data.

A. Organization and characteristics of your laboratory facilities. Provide:
   1. An organizational chart of the laboratory facilities. YES ✓ NO __
   2. Information on personnel qualifications. YES ✓ NO __
   3. Information on facilities and equipment. YES ✓ NO __
B. Laboratory procedures
   1. Identify the analytical method used for each compound. Include:
      (a) Target analyze(s).YES ✓ NO __

(b) Target tissue/species. YES ✓ NO __
(c) Performance standards. YES ✓ NO __

2. Explain the process to ensure that samples and their associated documentation are not interchanged. YES ✓ NO __
3. Explain how records are maintained. YES ✓ NO __
4. How are test results reported (include content and format.) YES ✓ NO __
5. Are corrective actions conducted for noted deficiencies? YES ✓ NO __
6. Does the laboratory participate in proficiency testing? If yes,
   (a) List the proficiency testing programs. YES ✓ NO __
   (b) Provide the most recent proficiency test report(s), including whether it passed or failed. YES ✓ NO __
7. Is the laboratory accredited? If yes, please provide:
   (a) The name of the accrediting body. YES ✓ NO __
   (b) When was the laboratory last accredited? YES ✓ NO __
   (c) What compound (class of compound) was the laboratory accredited for? YES ✓ NO __